March 6, 2026

Guangzhou Haoyimai Trading Co., Ltd.
℅ Aria Yao
Regulatory Affairs Specialist
Shenzhen Joyantech Consulting Co., Ltd.
1713a, 17th Floor, Block A, Zhongguan Times Square
Liuxian Ave., Xili Town, Nanshan District
Shenzhen, Guangdong 518000
CHINA

Re: K253983
Trade/Device Name: Water-based lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Received: December 12, 2025

Dear Aria Yao:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: The Center for Devices and Radiological Health (CDRH) does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253983

Device Name
Water-based lubricant

Indications for Use *(Describe)*
Water-based lubricant is a personal lubricant for penile, anal and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (K253983)

1. Date of Preparation

March 6, 2026

2. Submitter's Information

Applicant Name	Guangzhou Haoyimai Trading Co., Ltd.
Address	10th Floor, Building B, Shiliushe Industrial Zone, Xiamao Shixia Road, Baiyunhu Street, Baiyun District, Guangzhou
Contact person	Coco Ling
Phone	+86 139 0847 3323

3. Device Identification

Proprietary/Trade Name:	Water-based lubricant
Common Name	Personal lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name	Condom
Product Code:	NUC (lubricant, personal)
Review Panel:	Obstetrics/Gynecology
Regulatory Class:	II

4. Predicate Device Information

Trade Name	ID Free® Personal Lubricant
510(k) Number	K240745
Product Code	NUC
Manufacturer	Westridge Laboratories, Inc.
	The predicate device has not been subject to a design-related recall

5. Device Description

Water-based lubricant is a non-sterile, water-based personal lubricant for penile, anal and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Its formulation consists of purified water, 1,3-butanediol, propylene glycol, carbomer, glycerin, sodium hyaluronate, hydroxyethyl cellulose, sodium benzoate, sodium polyacrylate, citric acid, menthol, essence, and octyl hydroxamic acid.

The device specifications are listed in Table 1 below:

Table 1: Device Specifications for the Water-based lubricant

Property	Specification
Appearance	Viscous liquid
Color	Clear
Odor	Odorless
Viscosity per USP<911>	1-200 cPs
pH per USP <791>	5.0-6.5
Osmolality per USP<785>	1-200 mOsm/kg
Antimicrobial effectiveness per USP<51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show no less than 2.0 log reduction at 14 days and no increase from the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Total aerobic microbial count (TAMC) per USP<61> and <1111>	＜100CFU/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	＜10CFU/g
Absence of Pathogenic Organisms per USP<62>	Specification
Bile-Tolerant Gram negative bacteria	Absent
Staphylococcus aureus	Absent
Salmonella spp.	Absent
Escherichia coli	Absent
Pseudomonas aeruginosa	Absent
Clostridia	Absent
Candida albicans	Absent

6. Indications for Use

Water-based lubricant is a personal lubricant for penile, anal and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

7. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

The below table compares the intended use and technological characteristics of the subject and predicate device.

Comparison item	Subject Device: Water-based lubricant	Predicate Device: ID Free® Personal Lubricant (K240745)	Comments
Product Code	NUC	NUC	Same
Indications for Use	Water-based lubricant is a personal lubricant for penile, anal and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	ID Free® Personal Lubricant is a personal lubricant, for penile, anal and/or vaginal application intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Same
Water soluble	Yes	Yes	Same
Primary ingredients	Purified water, 1,3-butanediol, propylene glycol, carbomer, glycerin, sodium hyaluronate, hydroxyethyl cellulose, sodium benzoate, sodium polyacrylate, citric acid, menthol, essence, octyl hydroxamic acid	Water, Propanediol, Hydroxyethylcellulose, Carbomer, PEG 45M, EDTA, Tetrahydroxypropyl Ethylenediamene, Caprylhydroxamic acid, Sucrose	Different
pH	5.0-6.5	5.0 - 5.5	Different
Osmolality (mOsm/kg)	1-200	250 - 500	Different
Viscosity (mPa.s)	1-200	2,200 - 4,400	Different
Over the counter use	Yes	Yes	Same
Sterile	No	No	Same
Condom Compatibility	Latex, Polyisoprene	Latex, Polyisoprene	Same
Biocompatibility Test	Cytotoxicity (ISO 10993-5) Sensitization (ISO 10993-10) Acute Systemic Toxicity (ISO 10993-11) Vaginal Irritation (ISO 10993-23)	Cytotoxicity (ISO 10993-5) Sensitization (ISO 10993-10) Acute Systemic Toxicity (ISO 10993-11) Vaginal Irritation (ISO 10993-10)	Same
Antimicrobial Tested	Yes	Yes	Same
Shelf life	3 years	2 years	Different

The subject device and predicate device have the same intended use. The subject and predicate devices differ in ingredients, specifications (e.g., pH, osmolality, and viscosity), and shelf-life. These differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

8. Summary of Non-Clinical Testing

***Biocompatibility**

Biocompatibility testing was performed in accordance with the 2023 FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process", as follows:

- In Vitro Cytotoxicity Test, per ISO 10993-5:2009
- Skin Sensitization Test, per ISO 10993-10:2021
- Acute Systemic Toxicity Test, per ISO 10993-11:2017
- Vaginal Irritation Test, per ISO 10993-23:2021

The results of this testing demonstrated that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

***Shelf Life**

The subject device is a non-sterile personal lubricant with a 3 years shelf life based on the results of accelerated aging studies. Testing on the samples demonstrated that the subject device met all device specifications listed in Table 1 above across the device shelf-life.

***Condom Compatibility**

The compatibility of the subject device with condoms was evaluated in accordance with ASTM D7661-23, Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this testing indicate that the subject device is compatible with natural rubber latex and polyisoprene condoms, is not compatible with polyurethane condoms.

9. Conclusion

The results of the performance testing described above demonstrate that Water-based lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.